June 15, 2015

Dr. Lori White

Designated Federal Officer for the Board of Scientific Counselors (BSC)

Office of Liaison, Policy and Review

Division of National Toxicology Program (NTP)

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Submitted via email: whiteld@niehs.nih.gov

RE: PCACS Comments on Elk River chemical spill study for NTP Board of Scientific Counselors meeting, June 16, 2015

Dear Dr. White:

People Concerned About Chemical Safety (PCACS) is a community organization located in the Kanawha Valley that has been active in community affairs for over 25 years. We are dedicated to the protection of health and safety of all who reside, work, and study in the vicinity of chemical facilities. We promote chemical safety and actively work to prevent chemical disasters.

First and foremost, we want to acknowledge the tremendous amount of work performed by the National Toxicology Program and contributing scientists on this project. Around 300,000 of our family members and closest neighbors experienced this traumatic event; at least 1/3 of whom are documented as having experienced symptoms of exposure[1]. This chemical is one that has been identified as a risk by West Virginians for a number of years both in daily handling at work in coal processing facilities[2] and as a result of groundwater and

[1] http://www.kchdwv.org/KCHD/media/KCHD-Media/PDF Files/NACCHO-WV-Chemical-Spill-Webinar-SlidesRGAm.pdf

[2] http://www.businessinsider.com/mchm-is-nothing-new-in-our-water-2014-1?op=1

well contamination from coal mining practices.[3] We are deeply grateful for your work to help us better understand the significant gaps in our toxicological understanding of this chemical mixture.

Reports following the Elk River chemical leak indicate multiple symptoms and pathways of exposure[4]. However, at the core, the public's desire to have toxicological information on this chemical is to help them understand the potential long-term effects resulting from exposure to the chemical so that they can make informed decisions for their health and the health of their families. In reviewing the project findings, we are left with as many questions as we are answers. In assisting the public's navigation on the breadth of information that now exists, we seek greater details on the following areas.

INHALATION

In April 2014, Dr. Rahul Gupta, Kanawha-Charleston Health Department Director wrote a letter to EPA Administrator Gina McCarthy indicating the need for inhalation standards on crude MCHM and PPH.[5] It is our understanding that none of the studies performed by NTP were designed to examine inhalation toxicity yet this is one of the greatest pathways of exposure and an area of significant concern to many residents. Some of the highest peaks in patients seeking medical care following the Do Not Use order occurred during a flushing process[6][7] that instructed a 15-minute hot water flush in every home and business with no ventilation protocol[8]. Caution of inhalation exposure was advised on the Eastman chemical's MSDS sheet[9][10]. While past studies assume the spilled material to have the same fate properties regardless of temperature, a recent report from Virginia Tech and University of

[3] http://www.businessinsider.com/prenter-hollow-west-virginia-faces-contamination-2014-1?op=1
[4] http://pubs.acs.org/doi/abs/10.1021/es5040969
[5] http://www.kchdwv.org/KCHD/media/KCHD-Media/PDF Files/2014-04-29-EPA-Gina-McCarthy-Letter.pdf
[6] http://pubs.acs.org/doi/abs/10.1021/es5040969
[7] http://www.wvdhhr.org/Elk River Chemical Spill Health Effects - Findings of Emergency Department Record Review.pdf
[8] http://www.dhsem.wv.gov/WVTAP/testresults/Documents/POSTED 10 Home Study Interview Report_FINAL.pdf
[9] http://mediad.publicbroadcasting.net/p/wvpn/files/201401/MSDS-MCHM_I140109214955.pdf
[10] http://www.eastman.com/Products/Pages/ProductHome.aspx?Product=71014291&list=Chemicals

Memphis indicates differing fate properties[11] proving this previous hypothesis false. This indicates the potential for exposure concentrations to vary. Studies conducted in the last year under the guidance of Purdue University's Dr. Andrew Whelton identify that the compound's volatility increased as water temperature increased resulting in greater exposure.[12] Additional tests conducted by Northeastern University indicate that 4-MCHM may cause genotoxicity due to its DNA damage effect on human cells and therefore warrants further chronic carcinogenesis evaluation.[13]

We strive to understand NTP's decision not to conduct inhalation toxicity tests and implore you to take any steps necessary to do so.

METHYL 4-METHYLCYCLOHEXANECARBOXYLATE (MMCHC)

Just as little toxicological information was available for crude MCHM, the same can be said for MMCHC. And while disclosed as a component of crude MCHM, in the aftermath of the leak, CDC chose only to identify a screening level for crude MCHM, not MMCHC.[14][15] Yet, U.S. Geological Survey (USGS) studies clearly detected MMCHM in tap water samples[16] not previously reported. USGS and WV Testing Assessment Project (WV TAP) studies indicate that this chemical likely contributed to the odor[18][19] while comprising only 5% of the spilled material.[21] Once more, Purdue University, University of Memphis and Virginia Tech findings illustrate that MMCHC is more volatile crude MCHM. [22][23]

[11] http://pubs.acs.org/doi/abs/10.1021/acs.estlett.5b00061
[12] http://pubs.acs.org/doi/abs/10.1021/es5040969
[13] http://pubs.acs.org/doi/abs/10.1021/acs.est.5b00371
[14] http://emergency.cdc.gov/chemical/MCHM/westvirginia2014/mchm.asp
[15] http://actor.epa.gov/actor/GenericChemical?casrn=51181-40-9
[16] http://www.sciencedirect.com/science/article/pii/S0045653514012648
[18] http://www.usgs.gov/newsroom/article.asp?ID=4095&from=rss#.VXziJqY4qX0
[19] http://www.awwa.org/publications/journal-awwa/abstract/articleid/46969730.aspx
[21] http://pubs.acs.org/doi/ipdf/10.1021/es5040969
[22] http://pubs.acs.org/doi/ipdf/10.1021/es5040969
[23] http://pubs.acs.org/doi/abs/10.1021%2Facs.estlett.5b00061

In your proposed study plan, you indicated that MMCHC would be included in the Zebrafish study[25] yet the reported findings do not illustrate its inclusion.[27] We look forward to an explanation on the augmentation in your planned course of study. Since what we seek is to fully understand the public health impacts of our friends and neighbors resulting from this historically significant leak, we appeal to you to consider broadening the toxicological profile of MMCHC.

SYNTHESIS AND CHARACTERIZATION

In order to more fully understand NTP's findings on the toxicity of the chemical compound released during the Elk River chemical leak, we look forward to an explanation on your study's synthesis of the greater body of scientific evidence that has come to fruition since the incident as well as a full characterization of the compounds tested. In particular:

1. How did your studies take into account that findings of Purdue University,[28] Virginia Tech and University of Memphis that indicate varying fate properties[29]?

2. How did your studies take into account WV TAP findings that different concentrations of isomers were found in the crude MCHM and pure MCHM?[30]

3. How did your studies take into account the USGS findings on MMCHC?

4. At what temperatures was your testing administered and how does this replicate the exposure people experienced with warm water or hot water or showers?

5. How did you analytically confirm the chemical composition of the liquid used did not degrade or transform between receipt and all testing?

6. Are the toxicity studies realized in 2015 using the same exact liquid released in 2014?

[25] http://ntp.niehs.nih.gov/ntp/about_ntp/bsc/2014/dec/presentations/09bsc_auerbach_508.pdf
[27] http://ntp.niehs.nih.gov/ntp/research/areas/wvspill/zebrafish_update_508.pdf
[28] http://pubs.acs.org/doi/ipdf/10.1021/es5040969
[29] http://pubs.acs.org/doi/abs/10.1021%2Facs.estlett.5b00061
[30] http://www.awwa.org/publications/journal-awwa/abstract/articleid/46969730.aspx

7. Were your findings consistent with the Eastman studies provided to you?

8. What was the full characterization of the product available to you in the design of your studies? Has NTP received data on all tests conducted by Eastman on the chemical mixture spilled into the Elk River?

9. Would additional studies on toxicity or composition not previously provided by Eastman have helped you in the design of your tests?

10. What information would NTP need from officials to better design and interpret their studies?

11. What testing is being conducted that determines the toxicity of pure MCHM and crude MCHM are not different?

FINAL REPORT RECOMMENDATIONS

We look forward to the final report of your analysis and offer these final suggestions for your consideration.

1. On March 25th, WV TAP identified trace amounts of MCHM was trapped in West Virginia American Water's filters.[31] It wasn't until June 12, 2014, approximately 5 months after the leak was reported, that the filter change was complete.[32] We recommend that your findings result in final screening levels appropriate to the 2+ months of exposure to the crude MCHM, DiPPH, PPH and MMCHC.[33]
2. What is clear from your findings is the potential for teratogenic effects to occur as a result of exposure. In your final report, we encourage you to discuss how your findings pertain to our most vulnerable populations including infants and children, pregnant women, people with compromised immune systems and people who disproportionately experience cumulative chemical exposure such as workers and fenceline communities.

[31] http://www.wvgazette.com/News/201403250093
[32] http://www.amwater.com/wvaw/About-Us/news.html
[33] http://www.kchdwv.org/KCHD/media/KCHD-Media/PDF Files/2014-04-29-EPA-Gina-McCarthy-Letter.pdf

We also encourage you to include next step recommendations to assist in identifying research gaps that fully characterize the public health impacts recognized by CDC, KCHD as well as other researchers[34] caused by this incident.

3. Lastly, for any questions posed in this letter that are not addressed in your final reporting, we would appreciate a written response to this letter.

Please know that PCACS is deeply appreciative of this body's work. We look forward to the opportunity to engage you in a community dialogue around your findings and would be more than happy to assist you in facilitating such a gathering.

Sincerely,

[Redacted]

Maya Nye

President and Executive Director

[34] http://pubs.acs.org/doi/ipdf/10.1021/es5040969